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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,672	04/02/2001	Nabil Hanna	P 0280062 2000-30-0178A	9345

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MCLEAN, VA 22102

EXAMINER
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HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/17/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Applicati n No.

09/822,672

Applicant(s)

HANNA, NABIL

Examiner

Larry R. Helms

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): none.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: none.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 74-79, 81-87 and 89-96.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: It is still unclear if the cell line ATCC 69119 is publically available. The copy of the deposit from the ATCC does not confirm that all assurances have been met for the deposit. In addition US Patent 5,736,137 does not seem to disclose the entire amino acid sequence of the antibody including the constant regions. As to the 103 rejection the response again argues the references separately and states that Atlas does not teach the use of an anti-IL-10 antibody. While this is true the rejection is based on a combination of references. The response states that there is no evidentiary support for the downregulation of IL10 and this is only a proposal of the examiner. In response to this Atlas clearly teaches that IL-10 is a resistance factor and protects tumor cells from cytotoxic effects and as such it would be desirable to remove IL-10 as taught by Levy. The response then states that Levy does not suggest in vivo or therapeutic use of anti-IL-10 antibody. In response to this argument, Levy clearly teaches that in human pathology expression of bcl-2 has been implicated in lymphoma and use of an anti-IL-10 antibody established that IL-10 was responsible for upregulation of bcl-2. The response further states that Goldenburg teach multimodal therapy but teach away from the presently claimed invention. In response to this argument, Goldenburg teach multimodal therapy with anti-CD22 and chemotherapy. It is unclear how this teaches away from the invention. The response then states that that the prior art teaches away from the invention and Goldenburg teach away. In response to this argument, Bonnefoix has been addressed previously, Goldenburg, while he describes immunoconjugates of IL-10, in view of the findings of Levy and Atlas would make obvious the use of an anti-IL-10 antibody. The response then states that the claimed method produces unexpected results and the combination of C2B8 and an IL10 antagonist would be expected to have no greater therapeutic benefit than the use of C2B8 alone. In response to this argument, it would be expected that the combination of art cited would also be expected to produce such an effect. In addition there is no evidence presented in the specification that there is an unexpected synergistic effect.